

EFFICACY REVIEW

DATE: IN12-21-94 OUT 4-24-95

FILE OR REG. NO. 6148-RR

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED October 11, 1994

DATE OF SUBMISSION October 11, 1994

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): (I,)D, H, F, N, R, S Repellent

DATA ACCESSION NO(S). 433815-05;D210372;S478781;Case#031292;AC:166

PRODUCT MGR. NO. 10-Johnson/Tavano

PRODUCT NAME(S) Coppertone™ Sun & Bug Block

COMPANY NAME Schering-Plough Health Care Products, Incorporated

SUBMISSION PURPOSE Provide performance data in support of claims
for repellency against mosquitoes and duration
of protection against biting for new formulation.

CHEMICAL & FORMULATION N,N-diethyl-meta-toluamide 9.5%
Other isomers 0.5%
(Semi-aqueous, ready-to-use lotion, 1.048 Sp.Gr.)

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession
(MRID) Number 433815-05, having been obtained from a standard lab-
oratory repellency test conducted according to a protocol which
meets requirements of § 95-9(a)(2) and (3) on p. 263 and the stan-
dard of § 95-9(b)(1)(iv) on p. 264 of Product Performance Guide-
lines, as well as the GLP requirements of 40 CFR 160, are adequate
to support the claim for repellency against mosquitoes for the sub-
ject product when used according to label directions on human skin.
We note the inclusion of "deer ticks" among pests claimed for this
product, but without the usual accompanying phrase "which may carry
Lyme disease". The registrant should be informed that a claim for
deer tick entails submission of product specific efficacy data dem-
onstrating activity against nymphal Ixodes dammini, or presentation
of a rationale for claiming deer ticks on the basis of existing
registrations of similar or lower concentration of active ingredi-
ents. Presentation of such rationale would allow the claim for
carriers of Lyme disease to be added to the subject product label.

RL Vern L. McFarland, IRB